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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,010	ANDREASSON ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-48* is/are pending in the application.

4a) Of the above claim(s) *44-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, Claims 27-43 and a DNA encoding SEQ ID NO: 2, in the reply filed on 10/21/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is made FINAL.

Claims 27-48 are pending.

Claims 44-48 are withdrawn from consideration as being directed to the non-elected invention.

Claims 27-43 drawn to a DNA encoding SEQ ID NO: 2 are examined.

Claim Objections

Claims 28-30 and 41 are objected to for reciting non-elected inventions.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See for example page 34, line 26; and page 21, line 31. The specification should be checked for embedded hyperlinks and deleted.

The specification is also objected to for reciting sequence without a sequence identifier or SEQ ID NO. See for, example, page 16, lines 17-18; page 25, lines 6-7; page 39, line 24; and page 41, line 6. Nucleotide and /or amino acid sequences as used

in §1.821 through 1.825 are interpreted to mean unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides in patent applications. The 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Also, the sequence of Fig. 1(B) is not identified by SEQ ID NO: Applicant is respectfully requested to identify the sequences on pages 16, 25, 39, and 41 and on Fig. 1 (B) or to submit a new Sequence Listing, which comprises said sequences. The specification should also be amended to recite SEQ ID NO:

Information Disclosure Statement

The IDS of 08/23/06 has been considered; however, the items with hyperlinks have been lined through because the content and address of said hyperlink is subject to a change, introducing a new matter into the patent application. Applicant is therefore requested to delete any embedded hyperlink and/or other form of browser-executable code in the application. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a disease resistant transgenic plant comprising a

transgene encoding SEQ ID NO: 2, does not reasonably provide enablement for a transgenic plant comprising a transgene encoding a polypeptide comprising SEQ ID NO: 29 and SEQ IS NO: 30 or a conservatively substituted variant thereof, or a transgene that hybridizes to SEQ ID NO: 1 under strict hybridization conditions or a method of producing said transgenic plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to , inter-alia, a disease resistant transgenic plant comprising a transgene encoding a polypeptide comprising a conservatively substituted variants of SEQ ID NO: 29 and SEQ IS NO: 30 or a transgene that hybridizes to SEQ ID NO: 1 under strict hybridization conditions or a method of producing said transgenic plant. In contrast, the specification provides guidance for the transformation of plants with a construct comprising SEQ ID NO: 1 encoding SEQ ID NO: 2; wherein the expression of SEQ ID NO: 2 in the transgenic plant enhances disease resistance action of the plant and transgenic plants having enhanced disease resistance as result of expressing SEQ ID NO: 2. The specification also teaches that the N-terminal regions of SEQ ID NO: 2 of the invention (MKS1) interacts with the MPK4 (Examples 1-2; 5-6; Figure 5).

The specification, however, does not provide guidance for a transgenic plant comprising a transgene encoding a polypeptide comprising SEQ ID NO: 29 and SEQ ID NO: 30 that is other than SEQ ID NO: 2. The specification does not disclose sequences other SEQ ID NO: 2 comprising the two domains SEQ ID NO: 29 and 30 and conferring

disease resistance. The specification does not disclose a transgenic plant having disease resistance as a result of expressing a polypeptide comprising a conservatively modified variant of SEQ ID NO: 29 and SEQ IS NO: 30 or a transgene that hybridizes to SEQ ID NO: 1 under strict hybridization conditions or a method of producing said transgenic plant. The "conservatively substituted variant" is defined in the specification as a polypeptide sequence with individual conservative amino acid substitutions, deletions or additions. The specification discloses the mutation of five amino acids in the N-terminal region of SEQ ID NO: 2 corresponding to the pep22/domain 1 region that prevents the MKS1-MPK4 interaction. The specification, however, does not provide guidance for conservatively modified variants of exemplified or non-exemplified sequences that involves deletions or additions or even substitutions of other than the five amino acids in the N-terminal region of SEQ ID NO: 2 corresponding to the pep22/domain 1.

Furthermore, the specification does not provide guidance for a single variant of SEQ ID NO: 1 having the structural property, i.e, hybridizes to SEQ ID NO: 1 under strict hybridization conditions and encoding a polypeptide having the disease resistance activity of SEQ ID NO: 2. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40: 857-872) teach the identification of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65°C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and identified DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a

single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions, additions and deletions, as encompassed by the instant claims, and the regions within the a proteins' sequence where amino acid mutations can be made with a reasonable expectation of success in obtaining the desired function are limited in any protein and the results of such mutations are unpredictable.

Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires substantial guidance with respect to which amino acids in the protein's sequence, if any, would tolerate to modification, and detailed knowledge of the ways in which protein's structure relates to its function. In addition, making "conservative" substitutions does not usually produce predictable results. In the absence of such guidance, one skilled in the art would have to proceed with undue trial and error experimentation to screen through a vast number of nucleic acids that hybridize under any strict conditions including low, moderate and high conditions to SEQ ID NO: 1 and a vast number of nucleic acids encoding polypeptides with multiple amino acid modifications to identify those having the functional activity of SEQ ID NO: 2 . Undue experimentation would also be required which of those nucleic

acids would induce the desired disease resistance activity upon expression in a transgenic plant.

Therefore, given the breadth of the claims; the lack of guidance as discussed supra; the unpredictability with regard to amino acid modifications; and the limited working examples, the claimed invention is not enabled throughout the broad scope. See, *In re Wands* (*858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*. See also, *Amgen Inc. Chugai Pharmaceutical Co. Ltd*., 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 27-29, 31-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to, inter alia, transgenic plants comprising a multitude of sequences encoding polypeptides comprising SEQ ID NO: 29-30 or conservatively modified variants thereof or transgenes hybridize to SEQ ID NO: 1 under any strict hybridization conditions and a method of producing said transgenic plants. Applicant describes transgenic plants comprising a transgene encoding SEQ ID NO: 2 and methods of transforming plants with transgene. These are genus claims.

The claimed invention does not meet the written description requirement

because Applicant has not described a representative number of transgenes required for the production of claimed transgenic plants. Applicant has not described a single variant of SEQ ID NO: 1 having the structural properties as recited in the claims and that retains the desired function.

University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The specification does not describe the composition and structure of a transgene encoding a polypeptide comprising SEQ ID NO: 29-30 or conservatively modified variants thereof or transgenes that hybridize to SEQ ID NO: 1 under any strict hybridization conditions; said transgenic plant having disease resistance activity. A substantial variation in structures and function is expected among transgenes encoding polypeptides comprising SEQ ID NO: 29-30 or conservatively modified variants thereof or transgenes that hybridize to SEQ ID NO: 1 under any strict hybridization conditions. Since the transgenes are not described as broadly claimed, transgenic plants

comprising said transgene and a method of producing said transgenic plants are similarly not described.

Therefore, given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that Applicant was in possession of the invention as broadly claimed at the time of filing. See MPEP 2163.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1033 405 A2 (published 06/09/2000); Applicant's IDS).

According to the ISP provided by Applicant (see Documents submitted on 05/25/06), EP 1033 405 discloses a transgenic plant expressing a polypeptide sequence that is identical to SEQ ID NO: 2, and a plant transformation method; said transgene is operably linked to CaMV 35S promoter (see at least the claims and SEQ ID NO: 49382). Since the prior art transgenic plant is expressing a polypeptide

sequence that is identical to Applicant's SEQ ID NO: 2, the disease resistance activity is an inherent property. Therefore, EP1033405 teaches all claim limitations.

Claims 27-29, and 31-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryals et al (US 6091004 a).

Ryals et al teach a transgenic plant expressing an isolated SAR DNA from Arabidopsis encoding a polypeptide that regulates SAR and induces broad spectrum of disease resistance; said DNA is operably linked to a promoter that is pathogen inducible or CaMV 35S; and a method of transforming plants including dicots such as corn soybean sunflower, carrot and monocots such as corn, rice or sorghum with said DNA; said transgenic plants exhibit broad spectrum of disease resistance. The cited reference also teaches seed and progeny having disease resistance action of said transgenic plants; the cited reference further teaches that the expression of said SAR DNA can be incorporated by breeding approaches to produce progeny having disease resistance (see columns 25-27; 45-46 and Examples 20-25; and claims). Given that the definition of "conservatively modified variant" in the specification; and given the any "strict hybridization" conditions in the claims, the NIM1 gene from Arabidopsis of the prior art would hybridize to Applicant's SEQ ID NO: 1 under a strict hybridization conditions and would also encode a polypeptide comprising a conservatively modified variants of SEQ ID NO: 29-30 of the claims. Therefore, Ryals teach all claim limitations.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
6/18/2009

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638